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Attorneys for Defendants Accord Healthcare Inc. and Intas Pharmaceuticals, Limited

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ESPERION THERAPEUTICS, INC., Plaintiffs, v. ACCORD HEALTHCARE INC., INTAS PHARMACEUTICALS, LIMITED, Defendants.	Civil Action No.: 2:24-cv-06224 **DEFENDANTS' ANSWER TO COMPLAINT WITH AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Defendants Accord Healthcare Inc. and Intas Pharmaceuticals ("Accord"), through their undersigned counsel, hereby respond to the Complaint filed on May 16, 2024 (Dkt. 1) by Plaintiff Esperion Therapeutics, Inc ("Plaintiff") as follows[1]:

COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for patent infringement by Esperion Therapeutics, Inc. ("Esperion") under the patent laws of the United States, Title 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendants Accord Healthcare Inc. and Intas Pharmaceuticals Limited (collectively "Accord"). This action arises out of Accord's submission of Abbreviated New Drug Application ("ANDA") No. 219430 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of NEXLETOL® prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, and 11,926,584 (collectively, the "Asserted Patents").

ANSWER: Accord admits that Plaintiff's complaint purports to set forth an action for patent infringement under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq*. Accord admits that Accord Healthcare Inc. submitted an ANDA to FDA seeking approval for a generic version of NEXLETOL® ("Proposed ANDA Products") before the expiration of United States Patent Nos. 11,760,714 ("the '714 patent"); 11,613,511 ("the '511 patent"); and/or 11,926,584 ("the '584 patent) (collectively, "the Asserted Patents"). Accord denies any remaining allegations in Paragraph 1.

PARTIES

2. Plaintiff Esperion is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies them.

[1] The parties have stipulated to dismissal from this case of Defendant Intas Pharmaceuticals, Limited ("Intas"). *See* Dkt. No. 8, at 4 (Stipulation and [Proposed] Order Dismissing Without Prejudice Defendant Intas Pharmaceutical, Ltd. And Amending Case Caption to Reflect Same (June 5, 2024). However, the dismissal has not yet been ordered by the Court.

3. Upon information and belief, Defendant Accord Healthcare Inc. ("Accord Healthcare") is a corporation organized and existing under the laws of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

ANSWER: Accord admits that Accord Healthcare Inc. is a corporation organized and existing under the laws of North Carolina. Accord denies the remaining allegations in Paragraph 3.

4. Upon information and belief, Accord Healthcare is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

ANSWER: Accord admits that Accord Healthcare Inc. has sought approval for the manufacture, marketing, or sale of the Proposed ANDA products. Accord denies any remaining allegations in Paragraph 4.

5. Upon information and belief, Accord Healthcare directly or through its affiliates, markets and sells drug products throughout the United States, including in the state of New Jersey.

ANSWER: Accord admits that Accord Healthcare Inc. has sought approval for the marketing and sale of certain drug products. Accord denies any remaining allegations in Paragraph 5.

6. Upon information and belief, Defendant Intas Pharmaceutical Limited ("Intas") is a corporation organized and existing under the laws of India, having a place of business at Corporate House, Near Sola Bridge, S. G. Highway, Thaltej, Ahmedabad, 380054, Gujarat, India.

ANSWER: Paragraph 6 relates to Intas, which the parties have requested to be dismissed from the case according to the Parties' Stipulation. (Dkt. No. 8, at 4). No response is required from Accord Healthcare Inc. To the extent a response is required from Intas, admitted.

7. Upon information and belief, Intas is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

ANSWER: Paragraph 7 relates to Intas, which the parties have requested to be dismissed from the case according to the Parties' Stipulation. (Dkt. No. 8, at 4). No response is

required from Accord Healthcare Inc. To the extent a response is required from Intas, Intas admits that it manufactures pharmaceutical products pursuant to approved ANDAs. Intas denies any remaining allegations in Paragraph 7.

ANSWER:

8. Upon information and belief, Intas directly or through its affiliates, including Accord Healthcare, markets and sells drug products throughout the United States, including in the state of New Jersey.

ANSWER: Paragraph 8 relates to Intas, which the parties have requested to be dismissed from the case according to the Parties' Stipulation. (Dkt. No. 8, at 4). No response is required from Accord Healthcare Inc. To the extent a response is required from Intas, denied.

ANSWER:

9. Upon information and belief, Accord Healthcare is a wholly owned subsidiary of Intas.

ANSWER: Accord admits the allegations in Paragraph 9.

10. Upon information and belief, Intas directs or controls the operations, management, and activities of Accord Healthcare in the United States.

ANSWER: Accord admits that Accord Healthcare Inc. is a subsidiary of Intas Pharmaceuticals, Limited. Accord otherwise denies the remaining allegations in Paragraph 10.

11. Upon information and belief, Intas and Accord Healthcare are agents of each other and/or operate in concert as integrated parts of the same business group.

ANSWER: Accord admits that Accord Healthcare Inc. is a subsidiary of Intas Pharmaceuticals, Limited. Accord otherwise denies the remaining allegations in Paragraph 11.

12. Upon information and belief, Accord Healthcare and Intas act in concert to directly or through its affiliates market and sell drug products throughout the United States, including in New Jersey.

ANSWER: Accord admits that Accord Healthcare Inc. is a subsidiary of Intas Pharmaceuticals, Limited. Accord otherwise denies the remaining allegations in Paragraph 12.

13. Upon information and belief, Accord Healthcare and Intas work in concert on the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products for the United States market, including New Jersey.

ANSWER: Accord admits that Accord Healthcare Inc. is a subsidiary of Intas Pharmaceuticals, Limited. Accord otherwise denies the remaining allegations in Paragraph 13.

14. Upon information and belief, Accord Healthcare and Intas acting in concert prepared and submitted ANDA No. 219430 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLETOL® (the "Accord ANDA Product") prior to the expiration of the Asserted Patents.

ANSWER: Accord admits that Accord Healthcare Inc. submitted ANDA No. 219430 to FDA, seeking approval for the Proposed ANDA Product before the expiration of the Asserted Patents. Accord otherwise denies the remaining allegations in Paragraph 14.

15. Upon information and belief, Accord Healthcare and Intas acting in concert developed the Accord ANDA Product.

ANSWER: Denied.

16. Upon information and belief, Accord Healthcare and Intas acting in concert are seeking regulatory approval from the FDA to market and sell the Accord ANDA Product throughout the United States, including in New Jersey.

ANSWER: Accord admits that Accord Healthcare Inc. submitted ANDA No. 219430 to FDA, seeking approval for the Proposed ANDA Product before the expiration of the Asserted Patents. Accord otherwise denies the remaining allegations in Paragraph 16.

17. Upon information and belief, Accord Healthcare and Intas intend to obtain approval for Accord's ANDA No. 219430, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Accord ANDA Product in the United States, including in New Jersey.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 17, and therefore denies them.

JURISDICTION AND VENUE

18. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 18 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that Plaintiff's complaint purports to set forth an action for patent infringement under 35 U.S.C. § 271(e)(2). Further, Accord admits that this Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a) for claims under 35 U.S.C. § 271(e) relating to ANDA No. 219430 only. Accord denies any remaining allegations in Paragraph 18.

19. This Court has personal jurisdiction over Accord Healthcare for this action because Accord Healthcare, through its counsel, consented to personal jurisdiction in the District of New Jersey for purposes of this action prior to the filing of this Complaint.

ANSWER: Paragraph 19 contains legal conclusions to which no response is required. To the extent a response is required, denied. Accord does not contest personal jurisdiction for the purposes of this action only.

20. This Court also has personal jurisdiction over Accord Healthcare and Intas because both have litigated previous Hatch-Waxman patent litigation disputes in the District of New Jersey and consented to or did not contest personal jurisdiction in this Court for purposes of those actions including in at least *Fresenius Kabi USA, LLC v. Accord Healthcare Inc.*, C.A. No. 22-cv-06341, Dkt. 1 (D.N.J. filed Oct. 28, 2022); *Janssen Pharmaceuticals, Inc. et al. v. Accord Healthcare Inc.*, C.A. No. 22-cv-00856, Dkt. 1 (D.N.J. filed Feb. 16, 2022); *Eagle Pharmaceuticals, Inc. v. Accord Healthcare Inc.*, C.A. No. 19-cv-09031, Dkt. 11 (D.N.J. filed Apr. 15, 2019). Accord Healthcare and Intas have also affirmatively availed themselves of the jurisdiction of this Court by filing counterclaims in this Court including in at least *Otsuka Pharma. Co., Ltd. v. Intas Pharma. Ltd.*, C.A. No. 16-cv-5743, Dkt. 11 (D.N.J. filed Feb. 13, 2017); *Sanofi-Aventis US LLC v. Accord Healthcare, Inc.*, Civ. No. 14-cv-8079, Dkt. 9 (D.N.J. filed Feb. 10, 2015); *Otsuka Pharma. Co. v. Intas Pharm. Ltd., Accord Healthcare, Inc.*, C.A. No. 14-cv-3996, Dkt. 45 (D.N.J. filed Dec. 8, 2014).

ANSWER: Paragraph 20 relates to Intas, which the parties have requested to be dismissed from the case according to the Parties' Stipulation. (Dkt. No. 8, at 4). No response is required from Accord Healthcare Inc. Paragraph 20 contains legal conclusions to which no

response is required. To the extent a response is required, Accord admits that it is a party to the cases identified in Paragraph 20 and asserted counterclaims in some of the cases identified in Paragraph 20. Accord denies any remaining allegations in Paragraph 20. Accord does not contest personal jurisdiction for the purposes of this action only.

21. This Court also has personal jurisdiction over Accord Healthcare and Intas because, among other things, they have both, acting in concert, committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of ANDA No. 219430 in New Jersey, and intend to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219430, Accord Healthcare and Intas, acting in concert, will make, use, import, sell, and/or offer for sale the Accord ANDA Product in the United States, including in New Jersey, prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 21 relates to Intas, which the parties have requested to be dismissed from the case according to the Parties' Stipulation. (Dkt. No. 8, at 4). Paragraph 21 contains legal conclusions to which no response is required. To the extent a response is required, denied. Accord does not contest personal jurisdiction for the purposes of this action only.

22. Finally, this Court also has personal jurisdiction over Accord Healthcare and Intas because, among other things, this action arises from Accord Healthcare and Intas' actions directed toward New Jersey, and because, upon information and belief, Accord Healthcare and Intas have purposefully availed themselves of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey, including by, among other things, (1) intentionally marketing and providing its generic pharmaceutical products to residents of New Jersey; (2) enjoying substantial income from New Jersey; (3) creating a presence in New Jersey through its registration with the New Jersey Department of Health as a drug manufacturer and wholesaler and maintains a Drug and Medical Device Certificate of Registration under Registration No. 5003815; and (4) working in concert to develop and market pharmaceutical products, including in New Jersey, with their subsidiary Essential Pharmaceuticals LLC a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 8041 Arco Corporate Drive, Suite 200 Raleigh, NC 27617 and registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Entity ID No. 0600277360. https://www.essentialpharma.com/about/ (last visited May 14, 2024). Accord Healthcare and Intas therefore have purposely availed themselves of the benefits and protections of New Jersey's laws such that they should reasonably anticipate being hailed into court here.

ANSWER: Paragraph 22 relates to Intas, which the parties have requested to be dismissed from the case according to the Parties' Stipulation. (Dkt. No. 8, at 4). No response is required from Accord Healthcare Inc. Paragraph 22 contains legal conclusions to which no response is required. To the extent a response is required, denied. Accord does not contest personal jurisdiction for the purposes of this action only.

23. Upon information and belief, Intas' contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent Intas denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with New Jersey, this Court has personal jurisdiction over Intas pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) because Intas is not subject to the general jurisdiction of the courts of any state, and based on its contacts with the United States as a whole.

ANSWER: Paragraph 23 relates to Intas, which the partes have requested to be dismissed from the case according to the Parties' Stipulation. (Dkt. No. 8, at 4). No response is required from Accord. To the extent a response is required, denied. Intas does not contest personal jurisdiction for the purposes of this action only.

24. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for Accord Healthcare and Intas to litigate this action in this Court, and Accord Healthcare and Intas are subject to personal jurisdiction in New Jersey.

ANSWER: Paragraph 24 includes allegations as to Intas, which the parties have requested to be dismissed from the case according to the Parties' Stipulation, and no response is required from Accord. (Dkt. No. 8, at 4). Paragraph 24 contains legal conclusions to which no response is required. To the extent a response is required, denied. Accord does not contest personal jurisdiction for the purposes of this action only.

25. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

ANSWER: Paragraph 25 contains legal conclusions to which no response is required. Accord does not contest venue for the purposes of this action only.

26. Venue is proper in this Court because, among other things, Accord Healthcare, through its counsel, consented to venue in the District of New Jersey for purposes of this action prior to the filing of this Complaint.

ANSWER: Paragraph 26 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits to consenting to venue in the District of New Jersey for purposes of this action only.

27. Venue is also proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b) because Accord Healthcare and Intas have a regular and established place of business in New Jersey at least because, upon information and belief, they: (1) have sought approval from the FDA to market and sell Accord Healthcare and Intas' proposed generic NEXLETOL® product in New Jersey; and (2) have engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities.

ANSWER: Paragraph 27 includes allegations as to Intas, which the parties have requested to be dismissed from the case according to the Parties' Stipulation, and no response is required. (Dkt. No. 8, at 4). Paragraph 27 contains legal conclusions to which no response is required. To the extent a response is required, denied. Accord does not contest venue for the purposes of this action only.

28. Venue is proper in this Court as to Intas under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because, upon information and belief, Intas is a corporation organized under the laws of India, is not a resident of the United States, and thus may be sued in any jurisdiction. 28 U.S.C. § 1391(c)(3); HTC, 889 F.3d at 1354.

ANSWER: Paragraph 28 relates to Intas, which the parties have requested to be dismissed from the case according to the Parties' Stipulation. (Dkt. No. 8, at 4). No response is required from Accord. To the extent a response is required, Intas does not contest venue for the purposes of this action only.

THE PATENTS-IN-SUIT

29. U.S. Patent No. 11,760,714 (the "'714 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on September 19, 2023. A true and correct copy of the '714 Patent is attached hereto as "Exhibit A."

ANSWER: Accord admits that the '714 patent is entitled "Methods of Making Bempedoic Acid and Compositions of the Same" and that it issued on September 19, 2023. Accord admits that Exhibit A attached to the Complaint appears to be a copy of the '714 patent. Accord denies that the '714 patent was duly and legally issued. Accord denies any remaining allegations in Paragraph 29.

30. Esperion is the assignee of, and holds all rights, title and interest in the '714 Patent.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 30, and therefore denies them.

31. The '714 Patent currently expires on June 19, 2040.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 31, and therefore denies them.

32. U.S. Patent No. 11,613,511 (the "'511 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 28, 2023. A true and correct copy of the '511 Patent is attached hereto as "Exhibit B."

ANSWER: Accord admits that the '511 patent is entitled "Methods of Making Bempedoic Acid and Compositions of the Same" and that it issued on March 28, 2023. Accord admits that Exhibit B attached to the Complaint appears to be a copy of the '511 patent. Accord denies that the '511 patent was duly and legally issued. Accord denies any remaining allegations in Paragraph 32.

33. Esperion is the assignee of, and holds all rights, title and interest in the '511 Patent.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 33, and therefore denies them.

34. The '511 Patent currently expires on June 19, 2040.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 34, and therefore denies them.

35. U.S. Patent No. 11,926,584 (the "'584 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 12, 2024. A true and correct copy of the '584 Patent is attached hereto as "Exhibit C."

ANSWER: Accord admits that the '584 patent is entitled "Methods of Making Bempedoic Acid and Compositions of the Same" and that it issued on March 12, 2024. Accord admits that Exhibit C attached to the Complaint appears to be a copy of the '584 patent. Accord denies that the '584 patent was duly and legally issued. Accord denies any remaining allegations in Paragraph 35.

36. Esperion is the assignee of, and holds all rights, title and interest in the '584 Patent.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 36, and therefore denies them.

37. The '584 Patent currently expires on June 19, 2040.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 37, and therefore denies them.

38. All claims of the '714, '511, and '584 Patents are valid, enforceable, and not expired.

ANSWER: Denied.

ESPERION'S NEXLETOL PRODUCT

39. Esperion is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets life-saving pharmaceutical products, including NEXLETOL®.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 39, and therefore denies them.

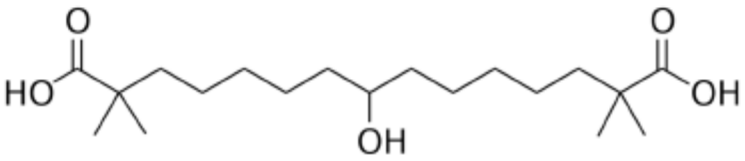
40. Esperion is the holder of New Drug Application ("NDA") No. 211616, which was approved by the FDA on February 21, 2020, for the marketing and sale of bempedoic acid in the United States under the trade name "NEXLETOL®." Esperion sells NEXLETOL® in the United States pursuant to NDA No. 211616.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 40, and therefore denies them.

41. NEXLETOL® (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated to 1) reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD and 2) as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

ANSWER: Accord admits that the Full Prescribing Information for NEXLETOL® states that NEXLETOL® is an adenosine triphosphate-citrate lyase (ACL) inhibitor. Accord admits that the Full Prescribing Information for NEXLETOL® states that NEXLETOL® is indicated to reduce the risk of myocardial infraction and coronary revascularization in adults who are unable to take recommended statin therapy with established cardiovascular disease and as an adjunct to diet to reduce LDL-C in adults with primary hyperlipidemia. Accord denies any remaining allegations in Paragraph 41.

42. Bempedoic acid, the active pharmaceutical ingredient in NEXLETOL®, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



ANSWER: Accord admits that the Full Prescribing Information for NEXLETOL® lists Bempedoic acid as the active pharmaceutical ingredient in NEXLETOL®. Accord admits that Bempedoic acid has the chemical name and structure described in Paragraph 42. Accord denies any remaining allegations in Paragraph 42.

43. The claims of the Asserted Patents cover NEXLETOL®.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 43, and therefore denies them.

44. The Asserted Patents have been listed in connection with NEXLETOL® in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

ANSWER: Admitted.

ACCORD'S ANDA PRODUCT

45. By letter dated April 2, 2024, and received by Esperion via Federal Express on April 3, 2024 (the "April 2nd Notice Letter"), Accord notified Esperion that Accord had submitted ANDA No. 219430 to the FDA for a generic version of NEXLETOL®.

ANSWER: Accord admits that Accord Healthcare Inc. sent a letter to Plaintiff on or about April 2, 2024, regarding the submission of ANDA No. 219430 to FDA seeking approval for the Proposed ANDA Product. Accord denies any remaining allegations in Paragraph 45.

46. In the April 2nd Notice Letter, Accord stated that ANDA No. 219430 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '714 and '511 Patents. Accord also contended that the '714 and '511 are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and/or sale of the Accord ANDA Product.

ANSWER: Accord admits that the letter sent to Plaintiff on or about April 2, 2024, regarding the submission of ANDA No. 219430, stated that ANDA No. 219430 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) contending the '714 and '511 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and/or sale of the Proposed ANDA Product. Accord denies any remaining allegations in Paragraph 46.

47. By letter dated April 23, 2024, and received by Esperion via Federal Express on April 23, 2024 (the "April 23rd Notice Letter"), Accord notified Esperion that Accord had submitted an amended patent certification to ANDA No. 219430.

ANSWER: Accord admits that Accord Healthcare Inc. sent a letter to Plaintiff on or about April 23, 2024, regarding the submission of an amended patent certification to ANDA No. 219430. Accord denies any remaining allegations in Paragraph 47.

48. In the April 23rd Notice Letter, Accord stated that it had submitted an amended certification to ANDA No. 219430 to also include a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent. Accord also contended that the '584 is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and/or sale of the Accord ANDA Product.

ANSWER: Accord admits that the letter sent to Plaintiff on or about April 23, 2024, regarding the amended patent certification to ANDA No. 219430, stated that Accord submitted the amended certification to ANDA No. 219430 to also include a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) contending the '584 patents is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and/or sale of the Proposed ANDA Product. Accord denies any remaining allegations in Paragraph 48.

49. The April 2nd and April 23rd Notice Letters state that Accord seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the Accord ANDA product before the expiration of the Asserted Patents. Upon information and belief, Accord intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Accord ANDA product promptly upon receiving FDA approval to do so.

ANSWER: Accord admits that Accord Healthcare Inc. sent a letter to Plaintiff on or about April 2, 2024, regarding the submission of ANDA No. 219430 to FDA seeking approval for the Proposed ANDA Product. Accord denies any remaining allegations in Paragraph 49.

50. By submitting ANDA No. 219430, Accord has represented to the FDA that the Accord ANDA Product has the same active ingredient, dosage form, and strength as NEXLETOL® and is bioequivalent to NEXLETOL®.

ANSWER: Accord admits the allegations in Paragraph 50.

51. Upon information and belief, Accord has knowledge of the Asserted Patents and had knowledge of at least the '714 and '511 patents when it initially submitted ANDA No. 219430 to the FDA.

ANSWER: Paragraph 51 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that the '714 and '511 patents were identified in FDA's Orange Book in connection with NEXLETOL®. Accord denies any remaining allegations in Paragraph 51.

52. Upon information and belief, Accord Healthcare intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product immediately and imminently upon approval of ANDA No. 219430.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 52, and therefore denies them.

53. Upon information and belief, Intas will manufacture the Accord ANDA Product and import the Accord ANDA Product to the United States for use, sale and offer for sale immediately and imminently upon approval of ANDA No. 219430.

ANSWER: Paragraph 53 relates to Intas, which the parties have requested to be dismissed from the case according to the Parties' Stipulation. (Dkt. No. 8, at 4). No response is required from Accord. To the extent a response is required, Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 53, and therefore denies them.

54. On or about May 3, 2024, pursuant to an Offer of Confidential Access, Accord produced portions of its ANDA No. 219430 to Esperion.

ANSWER: Accord admits the allegations in Paragraph 54.

55. This action is being commenced before the expiration of forty-five days from the date of Esperion's receipt of the April 2nd and April 23rd Notice Letters.

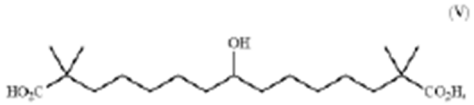
ANSWER: Accord admits that this action was commenced before the expiration of forty-five days from the date of the Notice Letters. Accord denies any remaining allegations in Paragraph 55.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,760,714

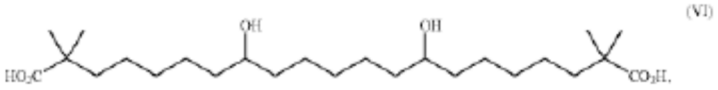
56. Esperion incorporates each of the preceding paragraphs 1 – 55 as if fully set forth herein.

ANSWER: Insofar as Plaintiff incorporates the allegations of the proceeding paragraphs 1 – 55 of the Complaint, Accord repeats and realleges its responses thereto, as if fully set forth herein.

57. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and a pharmaceutically acceptable excipient.

ANSWER: Accord admits that Paragraph 57 purports to set forth Claim 1 of the '714 patent. Accord denies any remaining allegations in Paragraph 57.

58. Accord's submission of ANDA No. 219430 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

59. Accord's commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product prior to expiration of the '714 Patent, and Accord's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

60. Upon information and belief, upon FDA approval of ANDA No. 219430, Accord intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Accord ANDA Product, unless enjoined by the Court.

ANSWER: Denied.

61. Upon information and belief, by virtue of their listing in the Orange Book and identification in Accord's April 2nd and April 23rd Notice Letters, Accord has knowledge of the Asserted Patents and knowledge that its Accord ANDA Product will infringe the Asserted Patents.

ANSWER: Paragraph 61 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that the '714, '584, and '511 patents were identified in FDA's Orange Book in connection with NEXLETOL®. Accord denies any remaining allegations in Paragraph 61.

62. Upon information and belief, Accord intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219430 is approved by marketing the Accord ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

ANSWER: Denied.

63. Upon information and belief, Accord intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219430 is approved, unless enjoined by the Court, because Accord knows that the Accord ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Accord ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

64. Accord's infringement is imminent because, among other things, Accord has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product before the expiration of the '714 Patent.

ANSWER: Denied.

65. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

ANSWER: Accord admits that there is a substantial and justiciable controversy between Plaintiff and Accord. Accord denies any remaining allegations in Paragraph 65.

66. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Accord's making, using, offering to sell, selling, and/or importing the Accord ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

67. Unless Accord is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

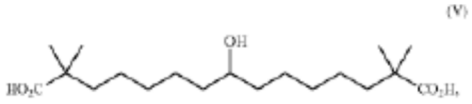
ANSWER: Denied.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,613,511

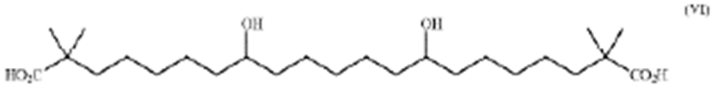
68. Esperion incorporates each of the preceding paragraphs 1 – 67 as if fully set forth herein.

ANSWER: Insofar as Plaintiff incorporates the allegations of the proceeding paragraphs 1 – 67 of the Complaint, Accord repeats and realleges its responses thereto, as if fully set forth herein.

69. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles (2θ): 10.3±0.2, 10.4±0.2, 17.9±0.2, 18.8±0.2, 19.5±0.2, and 20.7±0.2.

ANSWER: Accord admits that Paragraph 69 purports to set forth Claim 1 of the '511 patent. Accord denies any remaining allegations in Paragraph 69.

70. Accord's submission of ANDA No. 219430 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

71. Accord's commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product prior to expiration of the '511 Patent, and Accord's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

72. Upon information and belief, upon FDA approval of ANDA No. 219430, Accord intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Accord ANDA Product, unless enjoined by the Court.

ANSWER: Denied.

73. Upon information and belief, by virtue of their listing in the Orange Book and identification in Accord's April 2nd and April 23rd Notice Letters, Accord has knowledge of the Asserted Patents and knowledge that its Accord ANDA Product will infringe the Asserted Patents.

ANSWER: Paragraph 73 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that the '714, '584, and '511 patents were identified in FDA's Orange Book in connection with NEXLETOL®. Accord denies any remaining allegations in Paragraph 73.

74. Upon information and belief, Accord intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No. 219430 is approved by marketing the Accord ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

ANSWER: Denied.

75. Upon information and belief, Accord intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219430 is approved, unless enjoined by the Court, because Accord knows that the Accord ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the Accord ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

76. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

ANSWER: Accord admits that there is a substantial and justiciable controversy between Plaintiff and Accord. Accord denies any remaining allegations in Paragraph 76.

77. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Accord's making, using, offering to sell, selling, and/or importing the Accord ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

78. Unless Accord is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

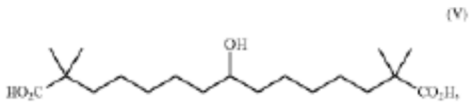
ANSWER: Denied.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 11,926,584

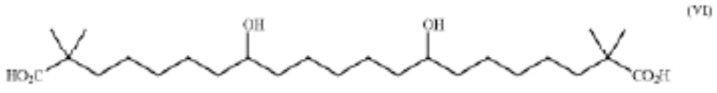
79. Esperion incorporates each of the preceding paragraphs 1 – 78 as if fully set forth herein.

ANSWER: Insofar as Plaintiff incorporates the allegations of the proceeding paragraphs 1 – 78 of the Complaint, Accord repeats and realleges its responses thereto, as if fully set forth herein.

80. Claim 1 of the '584 Patent claims a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



ANSWER: Accord admits that Paragraph 80 purports to set forth Claim 1 of the '584 patent. Accord denies any remaining allegations in Paragraph 80.

81. Accord's submission of ANDA No. 219430 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product before the expiration of the '584 Patent constituted an act of direct and/or indirect infringement of the claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

82. Accord's commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product prior to expiration of the '584 Patent, and Accord's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '584 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b), and/or (c).

ANSWER: Denied.

83. Upon information and belief, upon FDA approval of Accord's ANDA No. 219430, Accord will infringe at least claim 1 of the '584 Patent by making, using, offering to sell, and selling the Accord ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '584 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

ANSWER: Denied.

84. Upon information and belief, Accord specifically intends to, and will, actively induce infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(b) when ANDA No. 219430 is approved by marketing the Accord ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '584 Patent, unless enjoined by the Court.

ANSWER: Denied.

85. Upon information and belief, Accord's ANDA No. 219430 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Accord ANDA Product.

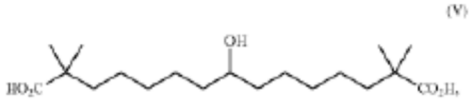
ANSWER: Accord admits that ANDA No. 219430 includes a proposed package insert with directions and instructions on proper utilization of the Proposed ANDA Product. Accord denies the remaining allegations in Paragraph 85.

86. Upon information and belief, upon FDA approval of ANDA No. 219430, Accord intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or

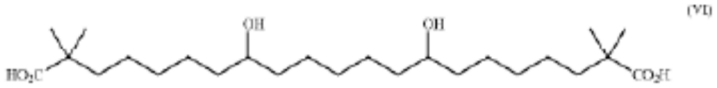
importing the Accord ANDA Product, unless enjoined by the Court, and the Accord ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 86, and therefore denies them.

87. On information and belief, the proposed package insert will include a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



ANSWER: Accord admits that ANDA No. 219430 includes a proposed package insert that will include a method of administering the Proposed ANDA Product to lower low-density lipoprotein cholesterol (LDL-C) in a human in need thereof. Accord denies the remaining allegations in Paragraph 87.

88. Upon information and belief, the use of the Accord ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '584 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

89. Upon information and belief, by virtue of their listing in the Orange Book and identification in Accord's April 2nd and 23rd Notice Letters, Accord has knowledge of the Asserted Patents.

ANSWER: Paragraph 61 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that the '714, '584, and '511 patents were identified in FDA's Orange Book in connection with NEXLETOL®. Accord denies any remaining allegations in Paragraph 89.

90. On information and belief, Accord is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Accord ANDA Product at least according to Accord's proposed package insert and, therefore, will directly infringe at least claim 1 of the '584 Patent.

ANSWER: Denied.

91. Upon information and belief, Accord intends to, and will, contribute to infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(c) when ANDA No. 219430 is approved, unless enjoined by the Court, because Accord knows that the Accord ANDA Product is especially made or adapted for use in infringing the â€™584 Patent, and that the Accord ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

92. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '584 Patent.

ANSWER: Accord admits that there is a substantial and justiciable controversy between Plaintiff and Accord. Accord denies any remaining allegations in Paragraph 92.

93. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Accord's making, using, offering to sell, selling, and/or importing the Accord ANDA Product, inducement thereof or contribution thereto, will infringe the '584 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Denied.

94. Unless Accord is enjoined from directly or indirectly infringing the '584 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER: Denied.

PRAYER FOR RELIEF

Accord denies that Plaintiff is entitled to any of the relief requested against Accord in Paragraphs 95 through 102 of the Prayer for Relief section of the Complaint.

GENERAL DENIAL

To the extent not specifically admitted above, including but not limited to every instance where Accord is without knowledge or information sufficient to form a belief about the truth of the allegations, Accord denies all allegations of the Complaint, including all headings to the extent the headings may be deemed allegations.

AFFIRMATIVE AND OTHER DEFENSES

In response to Plaintiff's Complaint, Accord asserts the following affirmative and other defenses. In asserting these defenses, Accord does not assume the burden of proof with respect to any issue upon which applicable law puts the burden of proof upon Plaintiff.

First Affirmative Defense
Failure to State a Claim

Plaintiff's Complaint, in whole or in part, fails to state a claim upon which relief may be granted.

Second Affirmative Defense
Non-Infringement of the '714 Patent

The submission of ANDA No. 219430 to FDA did not, and the importation, manufacture, use, offer for sale, or sale of the Proposed ANDA Product, will not infringe any valid and enforceable claim of the '714 patent under any section of 35 U.S.C. § 271, either literally or under the doctrine of equivalents.

Third Affirmative Defense
Non-Infringement of the '511 Patent

The submission of ANDA No. 219430 to FDA did not, and the importation, manufacture, use, offer for sale, or sale of the Proposed ANDA Product, will not infringe any valid and enforceable claim of the '511 patent under any section of 35 U.S.C. § 271, either literally or under the doctrine of equivalents.

Fourth Affirmative Defense
Non-Infringement of the '584 Patent

The submission of ANDA No. 219430 to FDA did not, and the importation, manufacture, use, offer for sale, or sale of the Proposed ANDA Product, will not infringe any valid and enforceable claim of the '584 patent under any section of 35 U.S.C. § 271, either literally or under the doctrine of equivalents.

Fifth Affirmative Defense
Invalidity of the '714 Patent

The claims of the '714 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq*.

Sixth Affirmative Defense
Invalidity of the '511 Patent

The claims of the '511 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq*.

Seventh Affirmative Defense
Invalidity of the '584 Patent

The claims of the '584 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq*.

Eighth Affirmative Defense
No Costs

Upon information and belief, Plaintiff is barred under 35 U.S.C. § 288 from recovering costs in connection with this action.

Ninth Affirmative Defense
Failure to State Claim of Willfulness

Plaintiff fails to state a proper claim for willful infringement or exceptional case under 35 U.S.C. §§ 271(e)(4) and 285, or otherwise.

RESERVATION OF DEFENSES

Accord reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional separate and/or affirmative defenses are appropriate, including, but not limited to, the defense of unenforceability.

COUNTERCLAIMS

For its counterclaims against Esperion Therapeutics, Inc. ("Esperion" or "Counterclaim Defendant"), Accord Healthcare Inc., ("Counterclaimant Accord") states as follows:

The Parties

1. Accord Healthcare Inc. is a corporation organized and existing under the laws of North Carolina, having a principal place of business at 8041 Arco Corporate Drive, Suite 200, Raleigh, NC 27617.

2. On information and belief, based on Counterclaim Defendant's allegation, Esperion Therapeutics, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150, Ann Arbor, MI 48108.

Nature of the Action

3. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and under the patent laws of the United States, 35 U.S.C. § 1 *et seq*.

4. Counterclaimant Accord seeks a declaration that it has not infringed, is not infringing, or will not infringe, directly or indirectly, any valid and enforceable claim of United States Patent Nos. 11,760,714 ("the '714 patent"), 11,613,511 ("the '511 patent"), and 11,926,584 ("the '584 patent") (collectively, "the Patents-in-Suit"), literally or under the doctrine of equivalents.

5. Counterclaimant Accord also seeks a declaration that the claims of the Patents-in-Suit are invalid under one or more sections of 35 U.S.C. § 101 *et seq*.

6. As a consequence of Counterclaim Defendant's Complaint against Counterclaimant Accord, and based on Accord's denials in its Answer, there exists an actual, continuing, and substantial case or controversy between Counterclaim Defendant and Counterclaimant Accord having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the alleged infringement of the Patents-in-Suit.

Jurisdiction and Venue

7. This Court has subject matter jurisdiction over these Counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Counterclaim Defendant has submitted to this Court's personal jurisdiction by suing Counterclaimant Accord in this District. On information and belief, Counterclaim Defendant sells products in this District, including the NEXLETOL® (bempedoic acid) product at issue in

this case, and conducts substantial business in, and has regular and systemic contacts with, this District.

9. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

Background

10. Esperion Therapeutics, Inc. is the holder of New Drug Application ("NDA") No. 211616 for NEXLETOL® (bempedoic acid) tablets.

11. The Patents-in-Suit are listed in the Orange Book for NEXLETOL®.

12. The face of the '714 patent, titled "Methods of Making Bempedoic Acid and Compositions of the Same," states that it issued on September 19, 2023.

13. Based on the face of the '714 patent, and on information and belief, Esperion Therapeutics, Inc. is the assignee of the '714 patent.

14. The face of the '511 patent, titled "Methods of Making Bempedoic Acid and Compositions of the Same," states that it issued on March 28, 2023.

15. Based on the face of the '511 patent, and on information and belief, Esperion Therapeutics, Inc. is the assignee of the '511 patent.

16. The face of the '584 patent, titled "Methods of Making Bempedoic Acid and Compositions of the Same," states that it issued on March 12, 2024.

17. Based on the face of the '584 patent, and on information and belief, Esperion Therapeutics, Inc. is the assignee of the '584 patent.

18. Accord Healthcare Inc. submitted ANDA No. 219430 to FDA seeking approval for a proposed generic version of NEXLETOL® ("Proposed ANDA Product") before the expiration of the Patents-in-Suit.

19. By a letter dated April 2, 2024 ("April 2 Notice Letter"), Counterclaimant Accord notified Counterclaim Defendant of the filing of ANDA No. 219430 with certifications provided

for in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that each claim of each of the '714 and '511 patents is invalid, unenforceable, and/or will not be infringed by the Proposed ANDA Product.

20. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), the April 2 Notice Letter included a detailed statement of the factual and legal basis for the certification that each claim of each of the '714 and '511 patents is invalid, unenforceable, and/or will not be infringed by the Proposed ANDA Product.

21. By a letter dated April 23, 2024 ("April 23 Notice Letter"), Counterclaimant Accord notified Counterclaim Defendant of the filing of ANDA No. 219430 with certifications provided for in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that each claim of each of the '584 patent is invalid, unenforceable, and/or will not be infringed by the Proposed ANDA Product.

22. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), the April 23 Notice Letter included a detailed statement of the factual and legal basis for the certification that each claim of each of the '584 patent is invalid, unenforceable, and/or will not be infringed by the Proposed ANDA Product.

23. The April 2 Notice Letter and April 23 Notice Letter also included an Offer of Confidential Access ("OCA") pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

24. Counterclaim Defendant accepted the OCA after negotiation and certain revisions to the terms thereof.

25. On or about May 3, 2024, Counterclaimant Accord produced its ANDA No. 219430 to Counterclaim Defendant for inspection pursuant to the OCA.

26. Counterclaim Defendant filed suit on May 16, 2024, alleging that Counterclaimant Accord infringed the Patents-in-Suit.

First Counterclaim
Declaratory Judgment of Non-Infringement of the '714 Patent

27. Counterclaimant Accord realleges Paragraphs 1-26 as if fully set forth herein.

28. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding non-infringement of the '714 patent.

29. Counterclaim Defendant has accused Counterclaimant Accord of infringing the '714 patent in connection with submission of ANDA No. 219430 and in connection with the prospective manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product if ANDA No. 219430 is approved.

30. The submission of ANDA No. 219430 to FDA does not infringe, directly or indirectly, any valid and enforceable claim of the '714 patent, either literally or under the doctrine of equivalents.

31. The manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product pursuant to ANDA No. 219430 have not and would not infringe, direct or indirectly, any valid and enforceable claim of the '714 patent, either literally or under the doctrine of equivalents.

32. Because Counterclaimant Accord has not infringed and will not infringe any valid and enforceable claim of the '714 patent, Counterclaim Defendant is not entitled to any damages or any other relief from or against Counterclaimant Accord.

33. Counterclaimant Accord is entitled to a declaration that the submission of ANDA No. 219430 to FDA does not infringe any valid and enforceable claim of the '714 patent.

34. Further, Counterclaimant Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Proposed ANDA Product have not

infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the ’714 patent.

Second Counterclaim
Declaratory Judgment of Non-Infringement of the ’511 Patent

35. Counterclaimant Accord realleges Paragraphs 1-34 as if fully set forth herein.

36. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding non-infringement of the ’511 patent.

37. Counterclaim Defendant has accused Counterclaimant Accord of infringing the ’511 patent in connection with submission of ANDA No. 219430 and in connection with the prospective manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product if ANDA No. 219430 is approved.

38. The submission of ANDA No. 219430 to FDA does not infringe, directly or indirectly, any valid and enforceable claim of the ’511 patent, either literally or under the doctrine of equivalents.

39. The manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product pursuant to ANDA No. 219430 have not and would not infringe, direct or indirectly, any valid and enforceable claim of the ’511 patent, either literally or under the doctrine of equivalents.

40. Because Counterclaimant Accord has not infringed and will not infringe any valid and enforceable claim of the ’511 patent, Counterclaim Defendant is not entitled to any damages or any other relief from or against Counterclaimant Accord.

41. Counterclaimant Accord is entitled to a declaration that the submission of ANDA No. 219430 to FDA does not infringe any valid and enforceable claim of the ’511 patent.

42. Further, Counterclaimant Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Proposed ANDA Product have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '511 patent.

Third Counterclaim
Declaratory Judgment of Non-Infringement of the '584 Patent

43. Counterclaimant Accord realleges Paragraphs 1-42 as if fully set forth herein.

44. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding non-infringement of the '584 patent.

45. Counterclaim Defendant has accused Counterclaimant Accord of infringing the '584 patent in connection with submission of ANDA No. 219430 and in connection with the prospective manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product if ANDA No. 219430 is approved.

46. The submission of ANDA No. 219430 to FDA does not infringe, directly or indirectly, any valid and enforceable claim of the '584 patent, either literally or under the doctrine of equivalents.

47. The manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product pursuant to ANDA No. 219430 have not and would not infringe, direct or indirectly, any valid and enforceable claim of the '584 patent, either literally or under the doctrine of equivalents.

48. Because Counterclaimant Accord has not infringed and will not infringe any valid and enforceable claim of the '584 patent, Counterclaim Defendant is not entitled to any damages or any other relief from or against Counterclaimant Accord.

49. Counterclaimant Accord is entitled to a declaration that the submission of ANDA No. 219430 to FDA does not infringe any valid and enforceable claim of the '584 patent.

50. Further, Counterclaimant Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Proposed ANDA Product have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '584 patent.

Fourth Counterclaim
Declaratory Judgment of Invalidity of the '714 Patent

51. Counterclaimant Accord realleges Paragraphs 1-50 as if fully set forth herein.

52. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding invalidity of the '714 patent.

53. The '714 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, including for the reasons stated in Accord's April 2, 2024 Notice Letter and Detailed Statement.

54. Counterclaimant Accord is entitled to a judicial declaration that the '714 patent is invalid.

Fifth Counterclaim
Declaratory Judgment of Invalidity of the '511 Patent

55. Counterclaimant Accord realleges Paragraphs 1-54 as if fully set forth herein.

56. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding invalidity of the '511 patent.

57. The ’511 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, including for the reasons stated in Accord’s April 2, 2024 Notice Letter and Detailed Statement.

58. Counterclaimant Accord is entitled to a judicial declaration that the ’511 patent is invalid.

Sixth Counterclaim
Declaratory Judgment of Invalidity of the ’584 Patent

59. Counterclaimant Accord realleges Paragraphs 1-58 as if fully set forth herein.

60. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding invalidity of the ’584 patent.

61. The ’584 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or 116 including for the reasons stated in Accord’s April 23, 2024 Notice Letter and Detailed Statement.

62. Counterclaimant Accord is entitled to a judicial declaration that the ’584 patent is invalid.

Prayer for Relief

WHEREFORE, Counterclaimant Accord respectfully requests that the Court award the following relief:

A. A declaration that by filing ANDA No. 219430, Counterclaimant Accord has not infringed, is not infringing, and will not infringe, directly or indirectly, any valid and enforceable claim of the Patents-in-Suit, literally or under the doctrine of equivalents, and that Counterclaimant

Accord has a lawful right to obtain FDA approval of its ANDA No. 219430 for bempedoic acid tablets;

B. A declaration that Counterclaimant Accord will not directly infringe, or contribute to or induce infringement of any valid and enforceable claim of the Patents-in-Suit, literally or under the doctrine of equivalents, by the importation, manufacture, use, offer for sale, or sale of the bempedoic acid tablets that are the subject of ANDA No. 219430;

C. A declaration that the Patents-in-Suit are invalid;

D. An injunction against Counterclaim Defendant, their officers, employees, agents, representatives, attorneys, and others acting on their behalf, from threatening or initiating infringement litigation against Counterclaimant Accord or its customers, suppliers, or any prospective or present sellers, distributors, or customers of Counterclaimant Accord, or charging them either verbally or in writing with infringement of the Patents-in-Suit with respect to the bempedoic acid tablets that are the subject of ANDA No. 219430;

E. A declaration that this is an exceptional case, and that the Counterclaimant Accord be awarded its attorneys' fees and costs pursuant to 35 U.S.C. § 285;

F. A declaration that Counterclaim Defendant are entitled to no damages, interest, costs, or other relief (including injunctive relief) from or against Counterclaimant Accord for infringement of the Patents-in-Suit;

G. An award of costs and expenses to Counterclaimant Accord; and

H. An award to Counterclaimant Accord of such further relief as this Court may deem necessary, just, and proper.

Dated: July 10, 2024

BENESCH FRIEDLANDER COPLAN & ARONOFF LLP

By: */s/ Kevin M. Capuzzi*

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Attorneys for Defendants Accord Healthcare Inc. and *Intas Pharmaceuticals, Limited.*

CERTIFICATE OF SERVICE

I hereby certify that on July 10, 2024, a copy of the foregoing *Defendants' Answer to Complaint with Affirmative Defenses and Counterclaims* was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's CM/ECF system.

/s/ Kevin M. Capuzzi
Kevin M. Capuzzi (NJ No. 173442015)

Attorney for Defendants Accord Healthcare Inc. and *Intas Pharmaceuticals, Limited.*